K011486

JUN 2 0 2001

SECTION 2

SUMMARY AND CERTIFICATION

510(k) SUMMARY

Submitted by:

Scott Matovich
Quantum Medical Imaging, LLC.
2905 Veterans Memorial Highway
Ronkonkoma, NY 11779 USA

May 10, 2001

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

Mark Camirand
Director of Q.A./Compliance
Phone: (631) 567-5800,
(631) 567-5074 (fax)

2. **Device Name and Classification:**

Trade Name:	Q-Rad Radiographic System
Classification Name:	Stationary X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680
Device Class:	Class II
Device Code:	90KPR

3. **Intended Use:**

The Quantum Medical Imaging, LLC Q-Rad System is a general-purpose radiographic, X-ray system used for acquiring radiographic exposures of various anatomical regions of the body.

4. Substantially Equivalent Devices:

Quantum Medical Imaging, LLC. believes the Q-Rad System is substantially equivalent to the following commercially distributed devices; Siemens MULTIX Compact K System (K001201) and Philips bucky DIAGNOST System (K945278)

5. Device Description:

The Q-Rad Radiographic System includes an X-ray generator cabinet and control console, patient support table, tube support device, wall-mounted radiographic cassette holder and other standard X-ray components. The Q-Rad Radiographic System fulfills its design requirements by providing the operator with the ability to perform safe and effective radiographic examinations.

6. Summary of Technological Characteristics as Compared with Predicate Device(s):

The Q-Rad Radiographic System has very similar technological characteristics as the predicate devices. The system contains the same basic configurations with the following standard components: radiographic table with cassette holder, wall-mounted cassette holder, tube support structure, X-ray tubes, collimator, and X-ray generator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2001

Mr. Scott Matovich
President
Quantum Medical Imaging, LLC
2905 Veterans Memorial Highway
RONKONKOMA NY 11779

Re: K011486
Q-Rad Radiographic System
Dated: May 11, 2001
Received: May 15, 2001
Regulatory Class: II
21 CFR 892.1680/Procode: 90 KPR

Dear Mr. Matovich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K011486

Device Name: Q-Rad Radiographic System

Indications for Use:

The Q-Rad Radiographic System is a stationary radiographic imaging system used for obtaining radiographic images of various portions of the human body.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011486